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Nicolaas Duncas

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28389

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02/26/2009

THE WEBB LAW FIRM, P.C.

700 KOPPERS BUILDING

436 SEVENTH AVENUE

PITTSBURGH, PA 15219

EXAMINER

KEMMERER, ELIZABETH

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The after final amendment and declaration filed under 37 C.F.R. § 1.132, both received 30 January 2009, have been entered.

Claim 36 remains rejected under 35 U.S.C. 103(a) as being unpatentable over either of Scott et al. or Yoshimura et al. in view of Kuberasampath et al., for reasons of record.

Applicant argues that the prior art teaches away from the claimed invention, since the prior art teaches use of a 100 kDa membrane, whereas the instant claim requires a 300 kDa membrane. This has been fully considered but is not found to be persuasive. Both the prior art and the instantly claimed method use a membrane to remove high molecular weight molecules. The only difference between the claimed invention and the prior art is the molecular weight cutoff value. The prior art retains only molecules below 100 kDa, whereas the instantly claimed method retains molecules below 300 kDa. This is simply a matter of degree. The desired osteogenic protein is isolated in the lower molecular weight fraction using either membrane.

Applicant also argues that the claimed method yields unexpected results. Specifically, Applicant urges that use of the 300 kDa membrane reduces transmembrane pressures, reduces the number of passes of the extract over the membrane, reduces the time necessary to complete ultrafiltration, and reduces the need for interventions to minimize fouling of the column by collagens and other aggregates. The Duneas declaration also addresses this at paragraph 7. This has been fully

considered but is not found to be persuasive. Similarly, the Duneas declaration under 37 CFR 1.132 filed 30 January 2009 is insufficient to overcome the rejection of claim 36 based upon 35 U.S.C. § 103(a) as set forth in the last Office action for the following reasons. These are the results that would have been expected by increasing the pore size for an ultrafiltration process. When isolating a small molecular weight protein, the use of larger pores has the benefits of requiring less pressure, being faster, and being less prone to clogging. These benefits are usually at the cost of purity. The skilled artisan would have been aware of these effects.

Applicant argues that the results were also unexpected in that four times more protein was produced using the 300 kDa membrane than the Kuberasampath method, and two times more protein was produced than when using a 100 kDa membrane. The Duneas declaration also addresses this at paragraph 5. Applicant also argues that the claimed method results in higher recovery of BMP than the prior art methods. The Duneas declaration addresses this at paragraph 6, and Figures 2a-d. This has been fully considered but is not found to be persuasive. Similarly, the Duneas declaration under 37 CFR 1.132 filed 30 January 2009 is insufficient to overcome the rejection of claim 36 based upon 35 U.S.C. § 103(a) as set forth in the last Office action for the following reasons. Once again, these are the results that would have been expected by increasing the pore size for an ultrafiltration process. When collecting a small molecular weight fraction during ultrafiltration, a smaller pre size results in higher purity but lower yield. Conversely, a larger pore size provides a larger yield, but at the cost of purity. The skilled artisan would have been aware of these effects. The choice of using a 100

kDa membrane or a 300 kDa membrane would have been an obvious matter of choice, readily made by the skilled artisan after weighing the known benefits and disadvantages of using smaller or larger pore sizes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ECK/
18 February 2009

/Elizabeth C. Kemmerer/
Elizabeth C. Kemmerer, Ph.D.
Primary Examiner, Art Unit 1646